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Inder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number, Application Number 10/734.671 Filing Date RANSMITTAL 12/12/2003 First Named Inventor **FORM** Foerster Art Unit 3736 **Examiner Name Apanius** or all correspondence after initial filing) Attorney Docket Number END-897DIV3 otal Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication to TC Drawing(s) Fee Transmittal Form Appeal Communication to Board Licensing-related Papers of Appeals and Interferences Fee Attached Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) Petition Amendment/Reply Petition to Convert to a **Proprietary Information** Provisional Application After Final Power of Attorney, Revocation Status Letter Change of Correspondence Address Affidavits/declaration(s) Other Enclosure(s) (please Identify Terminal Disclaimer below): Extension of Time Request Request for Refund **Express Abandonment Request** CD, Number of CD(s) ___ Information Disclosure Statement Landscape Table on CD Certified Copy of Priority Remarks Document(s) Reply to Missing Parts/ Incomplete Application

	Reply to Missing Parts under 37 CFR 1.52 or 1.53						
	SIGNA	TURE OF A	PPLICANT, A	TTORNEY, C	OR AGENT		
Firm Name	Welsh & Flaxman LLC					•	
Signature	M DE		~ _				<u> </u>
Printed name	Howard N. Flaxman						
Date	06/16/2008			Reg. No.	34,595		

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Date 06/16/2008

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number Complete if Known Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). **Application Number** 10/734,671 FEE TRANSMITT Filing Date 12/12/2003 For FY 2008 JUN 16 2008 First Named Inventor Foerster **Examiner Name Apanius** Applicant claims small entity status. See 37 CFR 1.27 Art Unit 3736 TOTAL AMOUNT OF PAYMENT (\$) 510.00 **END-897DIV3** Attorney Docket No. METHOD OF PAYMENT (check all that apply) Check ✓ Credit Card | Money Order None Other (please identify): Deposit Account Name: Welsh & Flaxman Deposit Account Deposit Account Number: 01-2221 For the above-identified deposit account, the Director is hereby authorized to: (check all that apply) Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee Charge any additional fee(s) or underpayments of fee(s) Credit any overpayments under 37 CFR 1.16 and 1.17 WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. **FEE CALCULATION** 1. BASIC FILING, SEARCH, AND EXAMINATION FEES **EXAMINATION FEES FILING FEES** SEARCH FEES **Small Entity Small Entity Small Entity** Fees Paid (\$) **Application Type** Fee (\$) Fee (\$) Fee (\$) Fee (\$) Fee (\$) Fee (\$) Utility 310 510 210 105 155 255 Design 210 105 100 50 130 65 160 80 Plant 210 105 310 155 620 310 510 310 Reissue 155 255 210 0 0 0 0 Provisional 105 **Small Entity** 2. EXCESS CLAIM FEES Fee (\$) Fee (\$) Fee Description 50 25 Each claim over 20 (including Reissues). 210 105 Each independent claim over 3 (including Reissues) 370 185 Multiple dependent claims Multiple Dependent Claims Fee Paid (\$) **Total Claims** Extra Claims Fee Paid (\$) Fee (\$) - 20 or HP = HP = highest number of total claims paid for, if greater than 20. Extra Claims Fee Paid (\$) Fee (\$) Indep. Claims _ - 3 or HP = HP = highest number of independent claims paid for, if greater than 3. 3. APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer

4. OTHER FEE(S) Non-English Specification, \$130	Fees Paid (\$)	
Other (e.g., late filing surcharge): A	510.00	
SUBMITTED BY	,	
signature 11	Registration No.	Telephone 703 920 1122

(Attorney/Agent)

listings under 37 CFR 1.52(e)), the application size fee due is \$260 (\$130 for small entity) for each additional 50

Number of each additional 50 or fraction thereof

(round up to a whole number) x

sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

/ 50 =

Extra Sheets

Total Sheets

Signature

- 100 =

Name (Print/Type) Howard N. Flaxman

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.

10/734,671

Applicant

Foerster et al.

Filed

12/12/2003

Group Art Unit:

3736

Examiner

Apanius

Docket No.

END-897DIV3

Customer No.:

021884

Title

METHODS AND DEVICES FOR DEFINING AND MARKING

TISSUE

APPEAL BRIEF

Mail Stop Appeal Brief - Patents Commissioner of Patents and Trademarks PO Box 1450 Alexandria, VA 22313-1450

Sir:

REAL PARTY IN INTEREST

Ethicon Endo-Surgery, Inc. is the real party in interest in the above referenced patent application.

06/17/2008 AWONDAF1 00000015 10734671 01 FC:1402

RELATED APPEALS AND INTERFERENCES

Neither Appellants' representative, Appellants' assignee, nor Appellants are aware of any appeals and/or interferences effected by or having a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claim 49 is currently pending and stand finally rejected. Claims 1-48 have been canceled.

Appellants accordingly appeal the Examiner's Final Rejection of claim 49.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the Final Rejection. As to the amendments filed prior to the Final Rejection, all amendments appear to have been entered and considered.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 49 is the only independent claim involved in the present Appeal. As such, claim 49 is summarized below. Claim 49 sets forth a delivery system (10) for delivering marker material (12) to a target site (51) within a patient. The delivery system (10) includes an elongate member (54) having a distal end, a discharge port in the distal end and an inner lumen (56) extending therein to and in fluid communication with the discharge port in the distal end. A mass of solid particulate marker material (one or more 12i) is disposed within the inner lumen (56). The delivery system (10) also includes an ejector (18, 24) which is advancable with and coupled to said elongate member (54) and which is configured to eject particulate marker material from the discharge port in said distal end of said elongate member (54). Support is found throughout the Specification as originally filed where the reference numerals listed above are used.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- 1. Whether claim 49 is unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
- 2. Whether claim 49 is unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 3,741,198 to Burton ("Burton") in view of U.S. Patent No. 5,123,414 to Unger ("Unger").

ARGUMENTS

I. CLAIM 49 IS IMPROPERLY REJECTED UNDER 35 U.S.C. § 112, 1st paragraph.

Claim 49 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Specification as originally filed clearly discloses that the numerous different markers contemplated by the inventors are to be delivered via a tube 54 having a lumen 56, thus the written description inherently has to provide support for each and every marker 12a-j being "disposed within an inner lumen of the elongated member" as this is the only delivery means disclosed. Specifically, on numerous occasions in the Specification, the markers are disclosed as being preloaded, deployed or traveling through a lumen or tube. Page 7, lines 17-19, states, "[i]n some embodiments, these deployment functions are communicated by means of the marker elements themselves travelling through the lumen for deployment from the distal region". Page 7, line 28, states, "...deployed from the lumen". Page 8, line 4, states, "...deployment from the lumen...". Page 15, lines 21-26, states, "[i]t is also within the scope of the invention to deliver the marker element through any tube which has access to the body or using optical medical instruments...through the body of the instrument". Page 17, lines 9-11, states, "...a plurality of marker elements 12b (two are shown, though any number may be employed) may be preloaded into tube 54b...".

Since the Examiner acknowledges that the disclosure supports a mass of solid particulate marker material, then it must also support delivering it via a tube and, in order to be delivered via the tube, the marker regardless of its form must at some point be disposed in the lumen in the tube.

One of ordinary skill in the art would surely be able to read the written description of the invention and then make and use what is claimed, which is all that 35 U.S.C. § 112, first paragraph requires. Therefore, the 112, 1st paragraph rejection is improper and should be reversed.

II. CLAIM 49 IS PATENTABLE OVER BURTON IN VIEW OF UNGER.

Claim 49 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Burton in view of Unger. Appellants have claimed a delivery as described above in the "Summary" section.

Burton has been relied upon as teaching a syringe filled with a mass of solid particulate marker material disposed within an inner lumen. Although the Examiner asserts that "it is respectfully submitted that any material that can be detected in some manner can be considered a marker", it is Appellants' opinion Burton does not teach a marker material. A marker as clamed in accordance with the present invention has a specific purpose of marking a site and not traveling from that site. Contrary to what the Examiner believes, just because something is detectable does not in turn make it a marker.

Appellant is delivering to a target site and not a moving site. If the marker were to move, it could no longer perform the function of marking the target site. Burton teaches a radiopaque contrast material in the form of a ferrofluid, which is a fluid containing magnetic particles for the purpose of moving the contrasting fluid up and down the spinal column. The ferrofluid may contain metallic particulate, but their purpose is not to mark. In fact, their purpose is to move the particles, and hence the fluid, along the spinal column during an examination. As such, Burton does not teach a marker and, in fact, teaches away from a marker. A marker as disclosed by Appellant is to mark a target site and Burton fails to teach marking a target site. With this in mind, Burton even if combined with Unger fails to teach the claimed invention.

Therefore, it is Appellants' opinion the rejection of claim 49 is improper and respectfully request the outstanding rejection be reversed.

II. CONCLUSION

In conclusion, Appellants have now shown that the §112 rejection is improper and the references cited by the Examiner neither disclose nor suggest the claimed invention. Therefore, it is respectfully requested that the outstanding rejections of claim 49 be reversed.

Respectfully submitted,

Howard N. Flaxman

Registration No. 34,595

Attorney for Appellants

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CLAIMS APPENDIX

- 1-48. (Canceled)
- 49. A delivery system for delivering marker material to a target site within a patient, comprising: an elongate member having a distal end, a discharge port in the distal end and an inner lumen extending therein to and in fluid communication with the discharge port in the distal end; a mass of solid particulate marker material disposed within the inner lumen; and an ejector which is advancable with and coupled to said elongate member and which is configured to eject particulate marker material from the discharge port in said distal end of said elongate member.

EVIDENCE APPENDIX

Not Applicable

RELATED PROCEEDINGS APPENDIX

Not Applicable